ASEPTIC ENCLOSURE FOR MEDICAL EQUIPMENT AND METHOD OF MAKING SAME

FIELD OF THE INVENTION

[00001] This invention relates to an aseptic enclosure for medical equipment and instruments and a method of forming such enclosures. The method of this invention is particularly adapted to form an aseptic enclosure which may be tailored to be received over and enclose particular designs of medical equipment and washed with an antiseptic solution for continued use following contamination. The aseptic enclosure of this invention further includes an audio warning system to signal when the enclosure should be replaced.

BACKGROUND OF THE INVENTION

[00002] Good medical practice now requires enclosure of medical apparatus and equipment with an aseptic or antiseptic enclosure. As used herein, "medical equipment" is intended to broadly cover any equipment or apparatus which is subject to biological or other contamination, including but not limited to equipment and apparatus used by the medical and dental professions. For example, medical equipment and apparatus in the surgical theater must be enclosed with an aseptic or antiseptic enclosure which is now replaced after each surgery. Such enclosures are generally formed by folding over a rectangular sheet of plastic and sealing the side edges, forming a rectangular bag. Such bag-like medical enclosures are not designed for a particular apparatus and therefore include loose side edges which require a medical technician to fold over the excess material which is then generally taped or otherwise secured to avoid contact by the medical personnel. Surgical procedure, for example, requires the surgeon and medical personnel in an operating theater to re-scrub if they contact the enclosure.

[00003] There is, therefore, a longstanding need for an improved medical enclosure which is tailored to enclose particular designs of medical equipment which does not include loose side edges and which conforms to the shape of the medical equipment to be enclosed. It would also be desirable to be able to clean such enclosures with an antiseptic solution for continued use. However, such enclosures are not suitable for reuse because the fastening means used to secure the sides of the enclosure, such as tape, may become contaminated. Finally, conforming the shape of the present enclosures to the shape of the medical equipment is a time-wasting and expensive procedure, particularly with the critical shortage of medical technicians.

[00004] The method of forming an aseptic enclosure for medical equipment of this invention solves these problems by providing a form-fitting aseptic enclosure for medical equipment which may be sterilized or disinfected for reuse and which preferably provides an audio warning when the enclosure should be replaced. Alternatively, the aseptic enclosure of this invention may be disposable.

SUMMARY OF THE INVENTION

[00005] The method of forming an aseptic enclosure for medical equipment of this invention includes heating a thin sheet or film of a thermoformable polymer to its thermoforming temperature. In the preferred embodiment, the thin polymeric sheet is a film of medical grade polymer having a thickness of between 4 to 6 mils (100 to 150 μ m), most preferably a polyolefin film. Medical grade polyolefin films are generally made of organic ethylene polymers which are translucent. As used herein, the term "aseptic," is intended to broadly cover polymeric sheets or film which are free from pathogenic microorganisms

including sterile applications. Most preferably, the aseptic sheet or film may be washed with an antiseptic solution for continued use as described further below.

[00006] The method of this invention then includes clamping a peripheral portion of the polymeric sheet or film at spaced locations while the sheet or film remains at the forming temperature. In the most preferred embodiments, the method includes clamping the sheet or film with an annular clamp. As will be understood, the shape of the annular clamp will depend upon the particular application for the aseptic enclosure. For example, the annular clamp may be rectangular to form an enclosure having a rectangular shape. But in the most preferred embodiment, the annular clamp is curvilinear, most preferably circular, wherein the annular clamp clamps the heated sheet or film from both sides and most preferably includes a vacuum to securely retain the film during forming.

[00007] The method of this invention then includes driving a platen having a diameter less than the distance between the spaced locations of the clamp having an outside diameter less than the inside diameter of the annular clamp against the heated sheet or film and through the plane of the sheet or film, thereby drawing the film, reducing its thickness, and forming a bag-like enclosure having a continual conical side wall integral with the end wall. In the most preferred embodiment, the platen has the same shape as the inside surface of the clamp, such that where the clamp is annular or circular, the outside surface of the platen is similarly shaped. As will be understood, the outside shape of the clamp is not material and the clamp may include, for example, a rectangular outside surface conforming to the shape of the sheet and a circular opening. In the most preferred embodiment, the platen has a flat or generally flat end surface, forming an enclosure having a flat bottom wall and a frustoconical side wall, wherein the minor diameter of the frustoconical side wall is

integral with the bottom wall formed by the platen and a major diameter at the opening to the enclosure. As will be understood, an aseptic enclosure having a generally circular bottom wall and a frustoconical side wall will conform to the shape of most medical equipment as defined above and eliminates the loose side edges of a rectangular enclosure which must be taped or otherwise secured to avoid contact with surgeons and other healthcare workers, thereby reducing cost and providing a more sterile atmosphere in a surgical theater, for example.

[00008] In the most preferred embodiments of the aseptic enclosures and methods of this invention, the enclosure may be washed with an antiseptic solution following a surgical procedure, for example, thereby reducing cost and saving labor. As set forth above, the aseptic medical enclosure of this invention eliminates the requirement for taping or other means of securing the side portions of a rectangular enclosure and therefore it is possible to continue use of the aseptic enclosure of this invention by wiping or cleaning the enclosure with an antiseptic, disinfecting or sterilizing solution. However, because the film following drawing is preferably relatively thin (*e.g.*, 1 to 2 mils), there is a limit to the number of times that the aseptic enclosure can be sterilized with a sterilizing solution. The most preferred embodiment of the aseptic enclosure of this invention therefore includes an audio warning system to alert the healthcare worker to replace the aseptic enclosure, which is preferably activated by repeated washings of the enclosure with an antiseptic solution.

[00009] The preferred embodiments of the aseptic enclosure of this invention includes a light-sensitive or light-actuated audio chip affixed to an outer surface of the enclosure coated with an opaque coating which is soluble or partially soluble in an antiseptic solution. The opaque coating preferably has a thickness

which may be tailored to a predetermined number of washings with an antiseptic solution, such as 3 to 5 or more washings. When the opaque coating is removed after a predetermined number of washings with an antiseptic solution, the light-sensitive audio chip will then provide an audio warning to replace the aseptic enclosure. In the preferred embodiment of the aseptic enclosure of this invention, the light-sensitive or light-actuated audio chip is imbedded in the generally flat end or bottom face of the enclosure, such that the face of the audio chip is flush with the outer surface of the bottom face of the enclosure. This not only makes it easier to wipe clean the end surface of the enclosure, but also avoids entrapment of microorganisms and other contaminants between the chip and the film.

[00010] The light-sensitive audio chip may be embedded in the polymeric film during the method of forming the enclosure of this invention, most preferably while the polymeric sheet or film remains at its thermoforming temperature. For example, a die member may be positioned opposite the platen and the light-sensitive audio chip may be placed on the die member, such that the light-sensitive audio chip is imbedded in the bottom wall of the enclosure during forming. The light-sensitive audio chip is then coated with an opaque coating soluble in a suitable antiseptic disinfectant or sterilizing solution either by spraying or painting.

[00011] The aseptic enclosure of this invention also preferably includes a means of securing the enclosure to the medical equipment to form fit the medical equipment enclosed. The securement means may comprise an elastic band, a drawstring or the like. In the preferred embodiment, an elastic band is applied to the side wall of the enclosure adjacent the open end. Other advantages and meritorious features of this invention will be more fully understood from the

following description of the preferred embodiments, the appended claims and the drawings, a brief description of which follows.

BRIEF DESCRIPTION OF THE DRAWINGS

[00012] Figure 1 is a side view of a conventional mobile imaging system including the aseptic enclosures of this invention;

[00013] Figure 2 is an end elevational view of one embodiment of the aseptic enclosure of this invention;

[00014] Figure 3 is a side cross-sectional view of the aseptic enclosure shown in Figure 2 in the direction of view arrows 3-3;

[00015] Figure 4 is an enlarged view of the portion identified by reference No. 4 in Figure 3;

[00016] Figure 5 is an enlarged view of Figure 3 as indicated by view arrow 5;

[00017] Figure 6 is a schematic side view illustrating the method of this invention;

[00018] Figure 7 is a top view of Figure 6;

[00019] Figure 8 is a schematic view of the method illustrated in Figure 6 following forming of the enclosure; and

[00020] Figure 9 is a schematic illustration of coating the light-sensitive audio chip.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[00021] As set forth above, the aseptic enclosure of this invention may be utilized to enclose medical equipment in various aseptic and sterile environments and may be cleaned or washed with an antiseptic solution for continued use following contamination. Figure 1 illustrates a typical use for the aseptic enclosure

of this invention, but should be considered for illustrative purposes only. Figure 1 illustrates a conventional mobile imaging system 20 for surgical and interventional procedures. The mobile imaging system 20 illustrated in Figure 1 includes a fluoroscopic head 22 and an intensifier head or tube 24. The fluoroscopic head 22 and intensifier 24 are supported on a rotational C-arm 26. The fluoroscopic head 22 and intensifier must be covered with a transparent aseptic enclosure for many surgical and medical applications. However, because the mobile imaging system forms no part of this invention, but is disclosed for illustrative purposes only, no further description of the mobile imaging system is required.

[00022] Figures 2 to 5 illustrate a preferred embodiment of the aseptic enclosure 30 of this invention which is also illustrated in Figure 1 enclosing the fluoroscopic head 22 and intensifier 24 of the mobile imaging system 20. The disclosed embodiment of the aseptic enclosure 30 includes a generally flat end or bottom wall 32 and a frustoconical side wall 34 integral with the end wall 32. The enclosure further includes an open end 36, wherein the end wall 32 is integral with the minor diameter of the frustoconical side wall 34 and the open end 36 is located at the major diameter of the frustoconical side wall 34. As will be understood, however, from the following description of the aseptic enclosure and method of this invention, Figures 2 and 3 illustrate the extended or expanded form of the aseptic enclosure 30 because the enclosure is formed from a thin polymeric film and the enclosure preferably includes a fastening means for securing the enclosure over a medical instrument. In the disclosed embodiment, the enclosure 30 includes an elastic band 38 as best shown at Figures 2 and 4 which is bonded to the frustoconical side wall 34 by adhesive or heat-bonded. As will be understood, the side wall 34 may be folded over the elastic band 38 (not shown), or other conventional

securement means including a drawstring may be substituted for the elastic band to retain the open end 36 to medical equipment, preferably providing an air seal to prevent escape or entry of microorganisms and other contaminants.

[00023] As set forth above, the most preferred embodiments of the aseptic enclosures of this invention also include an audio warning to alert healthcare workers that it is time to change the aseptic enclosure 30. In this embodiment, the audio warning is provided by a light-sensitive or light-actuated audio chip 40 which is imbedded in the end surface 32 of the aseptic enclosure 30 as best shown in Figure 5. The light-sensitive audio chip 40 is then coated with an opaque coating 42 which is soluble or partially soluble in a suitable conventional liquid antiseptic or disinfectant solution. The opaque coating 42 will then be removed following cleaning of the aseptic enclosure 30 with an antiseptic solution. In the preferred embodiment, the opaque coating 42 has a predetermined thickness, such that the opaque coating will be removed only after a predetermined number of washings with an antiseptic solution, such that the light-sensitive audio chip 40 will be exposed to light and provide a suitable audio warning as discussed further below.

[00024] Figures 7 to 9 illustrate one preferred method of forming the aseptic enclosure of this invention. The aseptic enclosure 30 shown in Figures 1 to 5 of this invention is formed from a thin sheet or film 44 of a thermoformable, preferably flexible polymer, preferably a medical grade polyolefin film and most preferably a metalocene polyethylene, such as MDF 7200 polyolefin film available from The Dow Chemical Company. The polyolefin film 44 is a tough soft flexible film having a thickness of between 4 to 6 mils. In mass production applications, the thin film 44 is received from a roll 46 to a heater 48 which heats the film to its thermoforming temperature which, in the case of metalocene polyethylene is about

120°F. The heater 48 may be any conventional heater including a conventional radiant or infrared heater.

[00025] The heated film 44 is then received in a die clamp assembly 50 which, in the disclosed embodiment, includes a stationary lower die clamp 52 and a moveable upper die clamp 54. In the preferred embodiment, the upper and lower die clamp members 54 and 52, respectively, are generally annular as shown in Figure 7, such that the die members fully clamp the heated film 44 and the inner surfaces 53 of the lower die member 52 and 55 of the upper die member 54 define an opening for receipt of the die platen 62 discussed below. As used herein, the term "annular" is intended to be broadly interpreted to include any generally ring-shaped clamp including opposed clamps having a rectangular opening or more preferably a circular opening as shown in the drawings. The outer shape of the die clamps may be any shape including circular or rectangular. In a most preferred embodiment, the lower die clamp 52 has a circular opening 53 having a smaller diameter than the circular opening 55 in the upper die clamp as shown. At least one of the die clamps is preferably connected to a source of vacuum 58 by line 56 as shown in Figures 6 and 8 to securely retain the film 44 during forming as described below. In the disclosed embodiment, the lower die clamp 52 is stationary and supports the heated film 44 and the upper die clamp 54 is moved to engage the film as shown by arrow 60 in Figures 6 and 8 and the ramparts in Figure 7. As will be understood, either die clamp member or both die clamp members 52 and 54 may be relatively moveable.

[00026] The heated film is then formed by a platen 62 preferably having a relatively flat end face 64 and a side face 66 having a configuration similar to the configuration of the openings 53 and 55 through the die clamp members 52

and 54, respectively. Thus, in the disclosed embodiment, the side face 66 of the platen 62 is cylindrical where the openings 53 and 55 through the die clamps 52 and 54 are circular or cylindrical as shown. Further, the diameter of the cylindrical side face 66 of the platen 62 is less than the smallest diameter of the cylindrical openings 53 and 55 and centered in the openings as shown. In the disclosed embodiment, the die platen 62 is supported on a ram 68, such that the end face 64 of the platen 62 is moveable to engage the film 44 and moves through the plane of the film 44, as shown by arrow 70 in Figure 8. The movement of the platen 62 deforms the heated film 44, as shown in Figure 8, and forms a frustoconical side wall 34 and the end face 64 of the platen 62 forms the generally flat end face 32 of the aseptic enclosure 30 described above in regard to Figures 2 and 3. In the disclosed embodiment, the platen 62 is also connected to the source of vacuum 58 by line 56, assuring full contact of the end face 64 of the platen 62 with the film 44. The outer edge of the frustoconical side wall 34 may then be die cut by a die member (not shown) which engages the upper surface of the lower platen 52 adjacent the opening 53 and a retaining means, such as the elastic strip 38 described above may be attached to the frustoconical side wall adjacent the opening 36 as described above.

[00027] In the most preferred embodiment of the aseptic enclosure 30 having an audio warning system as described above, the light-sensitive or light-actuated audio chip 40 may be imbedded in the end wall 32 of the aseptic enclosure during the forming process shown in Figures 6 to 8. In this embodiment, the forming apparatus includes a lower die member 72 opposite the die platen 62 having a flat upper end face 74 which includes the light-sensitive audio chip 40 as shown in Figures 6 and 8. In this embodiment, the lower die member 72 is preferably connected to a source of vacuum 76 by line 78, assuring that the heated film 34 is

drawn taught over the upper face 74 of the die member 72 and the light-sensitive audio chip 40 is embedded in the end face 32 of the aseptic enclosure as best shown in Figure 5. Finally, the light-sensitive audio chip 40 is coated with an opaque coating soluble or partially soluble in a suitable antiseptic or sterilizing solution as shown in Figure 9, wherein the opaque coating is sprayed onto the audio chip 40 by a nozzle 90 as shown. Alternatively, the opaque coating may be applied to the exposed surface of the light-sensitive audio chip 40 by any other suitable means including painting with a brush or the light sensitive audio chip may be purchased from the manufacturer precoated with an opaque coating.

[00028] Having described the preferred embodiments of the aseptic enclosure 30 and the method of forming the aseptic enclosure of this invention, it will be understood that various modifications may be made to the aseptic enclosure and method of forming the enclosure described above within the purview of the appended claims. In the preferred embodiment, the end wall 32 of the aseptic enclosure 30 is circular as best shown in Figure 2, which assures that the aseptic enclosure form-fits most medical equipment or apparatus, such as the head and intensifier of a mobile imaging system shown in Figure 1. However, as set forth above, the end surface may also be rectangular by utilizing a platen 62 having a rectangular end face and preferably annular die clamp members having rectangular openings as set forth above. Further, the side wall 34 of the enclosure is preferably frustoconical for ease of receipt of the enclosure on the medical apparatus. Where the film 44 initially has a thickness of between 2 to 4 mils as described above, the drawn aseptic enclosure 30 then has a thickness of between 2 to 3 mils. The light-sensitive or light-actuated audio chip may be any conventional sound chip of this type including conventional light-sensitive or light-actuated sound chips available

from various sources including Honsitak Electronics Co. Ltd. of Taipei, China. As will be understood by those skilled in this art, any audio message may be included in the light-sensitive or light-actuated sound chip. In the preferred embodiment, the audio message includes a warning to replace the aseptic enclosure following cleaning and washing with an antiseptic or disinfectant solution, such as chlorhexidine or alcohol.

[00029] The thickness of the opaque coating or "ink" will determine the number of washings with an antiseptic or disinfectant solution required to expose the light-sensitive face of the light-sensitive or light-actuated audio chip. Thus, the thickness can provide for any number of washings with a disinfectant or antiseptic solution, such as four to six washings. The audio chip then provides an audio "replacement warning" to the healthcare worker requiring the healthcare worker to replace the aseptic enclosure.

[00030] Finally, the method of forming an aseptic enclosure of this invention may also be modified within the purview of the appended claims. As set forth above, the film 44 is preferably heated prior to clamping and forming as shown in Figures 6 to 8. As set forth above, the die clamp is preferably annular, but may have any suitable shape, but the method of forming preferably draws a frustoconical side wall 34 as discussed above. The use of a vacuum on the die platen 62 and the clamp members 52 and 54 is optional. However, when the light-sensitive or light-actuated sound chip is imbedded in the end wall as disclosed, the lower die member 72 preferably includes a vacuum as disclosed to imbed the chip in the end wall of the enclosure. Alternatively, the light-sensitive audio chip may be affixed or embedded in the side wall, particularly where the side wall is more convenient to washing by the healthcare worker. Finally, the length of the frustoconical side wall

34 will depend upon the particular application and the stroke of the die platen 62. Having described the preferred embodiments of the aseptic enclosure and method of this invention, the invention is now claimed as follows.